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Competency Assessment: Strategies to Meet the Ongoing Challenge

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Abstract

Competency assessment should be a part of a laboratory's quality system and performance appraisal system—NOT a separate program.

Competency assessment should be an affirmation of staff competence, a positive morale builder.

After reading this article, the reader should understand the goals and basic parts of a positive competency assessment system that is integrated into the laboratory's quality system.

Compliance exam 110601 questions and corresponding answer form are located after the CE Update section on p. 179.

Why Do Competency Assessments?

In addition to meeting federal regulations and accreditation standards, a competency assessment program can help a laboratory reach other goals. Some of these goals are not required by any regulations but can help staff understand the importance of competency assessment and can help the staff work together better as a team. These goals include:

1. Assure staff and management (and the public) that competency exists and is documented.
2. Provide continuing education (CE) to employees.
3. Provide objective performance feedback to employees.
4. Help introduce new policies and procedures and review existing ones.

The federal regulations for competency assessment as stated in the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88) (enacted on February 28, 1992,[1] amended on January 19, 1993,[2] and revised on October 1, 2004[3]) can be accessed online at http://www.phppo.cdc.gov/clia/docs/42cfr493_2004.htm. Although it is important to be able to demonstrate to assessors and site surveyors that your laboratory staff is competent, that occurs only every 2 or 3 years. It is more important to continually assure each staff member that they can trust their peers to begin or complete laboratory procedures that a staff member may be assigned. Staff morale and productivity is negatively impacted when this trust does not exist. Identification of competence gaps and their immediate correction can reinstate this trust and improve morale. It is also important for laboratory managers, physicians, and all customers to be able to rely on this 24x7x365 competence.

What Are the Competency Regulations and Who Is Responsible?

The laboratory director's responsibilities include ensuring proper education, experience, and training of all personnel and ensuring that policies and procedures are established to monitor ongoing competency.[4] Part b8 of Section 1451 states that the technical supervisor is responsible for:

"evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately, and proficiently. The procedures for evaluation of the competency of the staff must include, but are not limited to –

(i) Direct observation of routine patient test performance, including patient preparation, if applicable, specimen handling, processing and testing;
(ii) Monitoring the recording and reporting of test results;
(iii) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records;
(iv) Direct observation of performance of instrument maintenance and function checks;
(v) Assessment of test performance through testing previously analyzed specimens (repeat testing), internal blind testing samples or external proficiency testing samples; and
(vi) Assessment of problem solving skills;"[5]

The next responsibility states that the performance of individuals responsible for moderate and high complexity testing must be evaluated and documented at least semiannually during the first year the individual tests patient specimens and at least annually thereafter unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.[6] A summary and analysis of competency assessments should be included in these performance appraisals.

In spite of numerous changes to the CLIA '88, the rules on competency assessment have not changed since first published in 1992—and they are the same for moderate complexity and high complexity testing. What has changed is the enforcement of the

rules. Many accrediting organizations, such as AABB, JCAHO, CAP, and COLA, have gained "deemed status" indicating their requirements are at least as stringent as the CLIA '88 regulations. Accrediting agencies may have additional competency requirements. No matter which agency accredits your laboratory, it is difficult to avoid the inevitable question: "Where are your competency assessment records?" Accreditors are looking for evidence of an ongoing program, not a single snapshot of the competency of a laboratory's staff.

Developing a Plan That Incorporates All 6 Components

After reviewing the regulations, each section of the laboratory should determine how it will incorporate each component into its competency assessment program. Remember that many of the aspects of your quality system may also qualify as competency assessment. It may be beneficial to make a 2-columned table with the 6 competency assessment components in the left column. Each laboratory section can write in the right column how it plans to assess each of the components. Think of each component as a different method of assessing competency, then look at the various procedures in the laboratory and determine which method would work best to evaluate the competency of the staff who perform each task. For example, phlebotomy and some "manual" procedures are best assessed by direct observation [component (i)]. The second component (monitoring the recording and reporting of test results) is probably already being done as part of the laboratory's quality assurance program. One can simply state how each staff member's ability to record and report test results is assessed and documented at least once per year.

Assessment of the third component (review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records) is similar. These records and results are most likely being reviewed (or should be), again, as part of your quality system. The important aspect of a competency assessment program is that each staff member's ability to perform these tasks (ie, perform intermediate steps of procedures, complete worksheets, perform and record quality control and proficiency testing, and complete preventative maintenance records) should be assessed and documented at least once each year.

The fourth component is direct observation of instrument maintenance and function checks. Each staff member should be observed performing at least 1 instrument maintenance or function check during a given year. The "direct observation" components (i and iv) are best and most objectively accomplished with the help of checklists. Any staff member can review the procedure to be assessed and list the key steps that should be observed in order to assess competency. Direct observation checklists need not be lengthy or detailed but should include "vulnerable" steps where, historically, errors have been made in the procedure. The checklist should include a conclusion (ie, a statement of whether or not the staff member was competent and what was done if not).

A great deal of competency can be assessed through the laboratory's proficiency testing program [component (v)] – especially if proficiency samples are rotated among all staff who perform each procedure and "leftover" specimens are repeated by other staff (AFTER results have been submitted!). The use of previously analyzed specimens (repeat testing) and internal blind testing samples can also be used to accomplish this component of the competency assessment program. Note the use of the word "or" in the Federal Register's wording in this component [as opposed to the word "and" in component (iii)]; it is not necessary to incorporate all 3 of these methods in your program.

Component (vi), assessment of problem solving skills, should not turn into a "stump the tech" exercise. Many of the tasks that laboratory staff members perform every day involve problem solving and these are what should be assessed. It is important to determine that each employee can recognize problems and resolve them or refer them to the appropriate individual. There are several ways this can be done:

1. Refer to your problem log (every laboratory should have one). You can copy an item from the log, indicate that the problem was adequately solved and/or appropriately referred to someone else, and file this in each person's competency assessment record. Examples include instrument malfunction, QC out of range, and specimen appropriateness. The responsibility of finding and copying a problem-solving item should be delegated to each employee.

OR

2. All employees can document some problem-solving incident that they have encountered during the year. Employees should write down the problem and the steps they took to resolve the problem. Examples of incidents include phlebotomy problems (unable to obtain sample, patient refused), specimen problems (inadequate amount, improper identification, hemolyzed), customer called with a question, and discrepancies with previous results. The supervisor (or designee) should document that the problem was appropriately handled and file this documentation in the employee's competency assessment record.

OR

3. A staff member can create a problem situation (such as any of the items listed in 1 or 2 above). All employees should write down the steps they would follow to resolve the problem. The supervisor (or designee) should document that the problem was appropriately handled and file this documentation in each employee's competency assessment record.

Employees should all be informed of the level of problem solving that is expected of them. If this was not done during new-employee orientation, it should be done as soon as possible—perhaps during each employee's annual performance appraisal. For example, all employees are expected to detect and report problems that apply to their job responsibilities; some are expected to detect and investigate problems; others to detect, investigate and at least begin solving the problem; others are expected to detect, investigate, and solve the problem. In all instances, employees need to be able to document the nature of the problem and what they did as follow-up.

Implementing a Plan

Once a competency assessment program has been established, members of the laboratory staff should be encouraged to develop and maintain one of the components of the program. Depending on their individual skills and interests, one may be interested in creating checklists for direct observations, another may prepare samples for repeat testing, and another may create a system for the assessment of problem-solving skills. The maintenance of a viable competency assessment program can be a team-building exercise within the laboratory.

Contingency plans should be established stating how a staff member who does not pass a competency assessment would be brought back to the "competent" status. In general, if a competency "failure" occurs, the staff member should not perform that procedure until corrective action steps have been taken and it is

later documented that the employee is competent. The employee's supervisor should determine the necessary corrective action steps and monitor their completion. These steps can range from reviewing the procedure manual to performing additional test procedures to partial or complete re-training.

Focused CE that is directed at correcting misconceptions and lack of consistency is key to maintaining staff competence. At the same time, reduced numbers of FTEs and shrinking CE budgets call for creative ways to provide CE for staff. Time is well spent and focused when staff members continue to learn about procedures they perform. Exercises that encourage staff members to study the procedure manual, become more consistent with other staff members, and understand the theory of the procedure contribute to productivity and fewer errors. The time spent completing competency exercises should be recorded as CE that counts toward the laboratory's required annual CE. The person who prepares each assessment exercise should determine the amount of CE time to be granted. Generally, a maximum of 0.5 hour CE should be granted per exercise. More than that works against staff productivity and may indicate that exercises are not focusing on specific problem-prone portions of procedures.

The results of competency assessment exercises should be included in each employee's annual performance appraisal and rolled into the total quality system. Employees receive positive feedback for all exercises completed correctly (hopefully, the vast majority) and also receive specific information on things they need to correct or improve. This objective data makes performance appraisals easier for management and more meaningful to employees. Other appraisal information can be gathered simultaneously: Are assignments completed on time? Has the employee volunteered to prepare any of the exercises? Can the employee find information in procedure manuals? Does the employee ask questions when appropriate?

Competency assessment exercises can also be used to introduce new policies and procedures and to review existing ones. The CLIA regulations state that, prior to reporting out results, it should be documented that new employees (or employees being trained in a new area or on a new instrument or procedure) are competent to perform the procedures for which they are responsible and that performance must be assessed at least semiannually during the first year.[7] This second assessment should occur sometime within a calendar year (Refrain from stating that it must be done at "6 months"; you will be unnecessarily constraining yourself.) All laboratories have some procedures that do not change. They should be reviewed periodically—perhaps a few each year. For efficiency, only assess problem-prone parts of these procedures to assure that everyone is still performing them correctly.

Testing Personnel

Although it was first thought that the term "testing personnel" (the term used in the Federal Register) referred only to those who actually perform laboratory tests, closer examination of the document reveals an explanation of the term. "Testing personnel" refers to anyone involved in any 1 of 3 phases: preanalytic, analytic, and postanalytic—think of it as "vein to brain." This includes all staff who collect and process specimens, those who perform test procedures as well those who report test results (via hard copies, a computer, over the telephone or in person).

What about physicians? Some laboratories include pathologists in their competency assessment program; some hospitals and clinics include physicians (and others) who perform provider-performed microscopy (PPM) and other testing in the laboratory's program. On the other hand, the medical staff's credentialing process can be used to document the competency of physicians. Any of these methods meets the CLIA or JCAHO requirement for competency assessment.[8,9]

Summary

An excellent resource on this subject was published in 2004 by CLSI.[10] I would also highly recommend an article published in 2004 by Sharp and Elder.[11] It is an extensive discussion of competency assessment in general, providing specific examples for implementing it in the clinical microbiology laboratory. The examples are easily transportable to other areas of the laboratory. Another excellent article by Tiehen[12] addresses competency assessment in the laboratory. Both articles contain sample forms for documenting assessments and many helpful references. There are also several competency assessment packages available for purchase. They can be found by conducting an Internet search using words such as "laboratory competency assessment."

Competency assessment does not have to consume a large amount of time, effort, or money. An overall laboratory policy should be in place that states the components and time intervals of the program. Each section of the laboratory should have a competency assessment procedure and an annual plan that states how each component will be accomplished. All checklists and forms used to record competency assessments should include an evaluation statement that indicates whether or not the staff member was deemed competent. A summary of each employee's competency assessment should be included in their annual performance appraisal. As long as the laboratory maintains a record of what was done each year, individual records can be discarded after 2 years, like other quality control records—unless your laboratory's accrediting agency states otherwise.

The main goal of a competency assessment program should be to efficiently assess and document the competency of the laboratory staff. This reassures staff, management, accrediting agencies and the public of the competence of individuals who provide laboratory results that guide the health maintenance, diagnosis and treatment for those within the health care system.

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